

### **REMARKS/ARGUMENTS**

In response to the prior Office Action, independent claim 10 was amended to incorporate limitations from allowed claim 17, and independent claim 28 was amended to incorporate limitations from allowed claim 35. The Examiner has now withdrawn the allowability of claims 17-18 and 35-36, in view of the newly discovered reference to Esch et al. (U.S. Patent No. 4,205,043). In particular, the Examiner now rejects claims 10-11, 13-14, 18, 28-29, 31-32 and 36 as being obvious in view of the combined teachings of U.S. Patent No. 5,789,175 to Priest and U.S. Patent No. 4,205,043 to Esch et al. Moreover, claims 10-11, 13-14, 16, 28-29, 31-32, 34, and 36 have been rejected under 35 U.S.C. 103(a) as being obvious in view of the combined teachings of U.S. Patent No. 6,087,089 to Wu, U.S. Patent No. 2,232,622 to Moses et al., and U.S. Patent No. 4,205,043 to Esch et al. Furthermore, claims 12, 15, 30, and 33 have been rejected under 35 U.S.C. 103(a) as being obvious in view of the combined teachings of Wu, Moses et al., Esch et al., and either of U.S. Patent No. 5,770,150 to Thornton et al. or U.S. Patent No. 6,488,890 to Kirchhof.

It is respectfully submitted that none of the cited references, taken individually or in combination, teaches or suggests the applicant's invention as set forth in the present claims.

#### **35 U.S.C. 103 Rejection Based Upon Priest and Esch et al.**

In rejecting independent claims 10 and 28 as obvious in view of Priest and Esch et al., the Examiner has relied upon Priest as the primary reference, and argues that "[i]t would have been obvious to one of ordinary skill in the art to employ an indicator assembly as taught in Esch et al., in the system of Priest because it would provide an inexpensive, yet accurate means of tracking the concentration and exposure time of the sterilization process in a staged, profiled manner."

#### **Priest**

Priest discloses a pressure actuated device applicable to *sterilization systems* and chemical treatment processes *in the sterilization arts* (see column 1, lines 5-12). In this regard, Priest's indicator detects a series of evacuation and *sterilization pulses* in a *sterilization process* (see column 1, lines 53-56). Accordingly, Priest's pressure activated chemical indicator "is provided for indicating multiple exposures to a *sterilant vapor*," (see column 1, lines 60-62).

More specifically, Priest discloses a pressure actuated chemical indicator that includes: (1) a pressure extensible member that extends and contracts with changes in pressure in a processing chamber; (2) a chemical integrator; and (3) a drive mechanism powered by the expansion and contraction of the expansible member to index portions of the chemical integrator to be exposed to the processing chamber through a window (see column 2, lines 10-16). The extensible member extends in response to a pressure drop, and the extendable member contracts in response to an increase in pressure in the processing chamber. The expansion and contraction of the extensible member is converted into relative movement of the chemical integrator and the window, bringing a subsequent region of the chemical integrator into alignment with the window to be exposed to the gaseous or vaporized *sterilant chemical* in the processing chamber. A plurality of regions of the chemical integrator are exposed to the gaseous or vaporized *sterilant chemical* in the processing chamber. See column 2, lines 16-30. Accordingly, Priest's invention is used to detect whether the required pressures and chemical vapor concentrations are achieved in a *sterilization system* (see column 1, lines 44-48).

In view of the foregoing, it is respectfully submitted that Priest's pressure actuated chemical indicator is for use in a controlled "*sterilant receiving environment*" (see column 1, line 64) wherein there is a pressure change during a *sterilization process* using a *sterilant vapor* (e.g., hydrogen peroxide vapor).

**Esch et al.**

In significant contrast to Priest's device, Esch et al. discloses a badge for determining human exposure to toxic gases encountered in a *fire atmosphere*. Esch et al. notes in the "Background and Summary of the Invention" that (emphasis added):

*Fire atmospheres* to which *firefighters* are exposed commonly include toxic gas components. For example, many *fireman* are injured as a result of contact with hydrochloric acid gases formed when polyvinyl resins are burned. Accordingly, it is desirable to be able to detect the presence of toxic gases and monitor the exposure dosage to the gas.

Esch et al. recognize that "the presently available apparatus for sampling *fire atmospheres* are either too cumbersome, too fragile, or too expensive for *generalized field use*" (emphasis added). Esch et al. envision that "the badge can be mounted by adhesive or by a suitable clip-on, for example, a hat or the sleeve of a *firefighter*." Accordingly, Esch et al. teach

that the badge may include a clip that can be used to engage an article of clothing of the firefighter. In view of the foregoing, it is respectfully submitted that Esch et al. is directed to a badge indicator device that is to be worn by a human as they are exposed to a "*fire atmosphere*" to determine human exposure to toxic gases produced by a fire.

Moreover, the "badge detectable gasses" identified in Table I (see column 3) include only toxic gasses that would be encountered in a fire atmosphere. Hydrogen peroxide or any chemistries that include hydrogen peroxide do not appear on the list of "badge detectable gasses" of Table I. It is further noted that, the preamble of the sole independent claim (i.e., claim 1) is directed to an "apparatus for indicating hazardous atmospheric conditions in a *firefighting environment*, consisting essentially of...."

In summary, Esch et al. is directed to a badge indicator that is to be worn by a human that will be entering a "*fire atmosphere*" wherein there is potential exposure to airborne toxic gasses produced by a *fire*. In contrast, Priest is concerned with detecting whether the required pressure and *sterilant vapor concentrations* are achieved in a *sterilant receiving environment* during a controlled *sterilization* process.

#### **Requirements for Establishing Prima Facie Case of Obviousness**

As the Examiner is well aware, the law concerning the establishment of a *prima facie* case of obviousness has several requirements. As stated in MPEP § 2142 three basic criteria must be met (emphasis added):

First, there must be some *suggestion or motivation*, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, *to modify the reference or to combine reference teachings*. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must *expressly or*

*impliedly suggest* the claimed invention or the examiner must present a *convincing line of reasoning* as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

As further stated in MPEP § 2143.01, the prior art must suggest the desirability of the claimed invention in making a *prima facie* case of obviousness. In this regard (emphasis added):

“There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.” *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious (sic) was held improper.).

“In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification.” *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some *teaching, suggestion, or motivation* to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. “The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.” *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000).

Moreover, it should be appreciated that “the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggest the desirability of the combination” *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

As discussed above, the Examiner has argued that "it would have been obvious to one of ordinary skill in the art to employ an indicator assembly as taught by Esch et al., in the system of Priest because it would provide an inexpensive, yet accurate means of tracking the concentration and exposure time of the sterilization process in a staged, profiled manner." Accordingly, it appears that the Examiner is supporting the combination of the Priest and Esch et al. references under 35 U.S.C. 103 based upon the rationale that because Esch et al. discloses an "inexpensive" indicator that one skilled in the art would be motivated to combine the teachings of Priest and Esch et al. It is respectfully submitted that the mere fact that the badge disclosed by Esch et al. can be manufactured inexpensively does not provide the motivation to one skilled in the art to apply certain elements of the badge taught by Esch et al. to the pressure actuated sterilant indicator taught by Priest.

It remains unclear from the Examiner's reasoning why one skilled in the art, without benefit of hindsight, would combine select teachings of Esch et al. with the pressure actuated sterilant indicator of Priest. As discussed above in detail, Esch et al. is directed to a badge for determining human (i.e., firefighters) exposure to toxic gasses found in a *fire atmosphere*. In contrast, Priest is directed to a pressure actuated *sterilant* indicator that detects whether the required pressure and *sterilant* vapor concentrations are achieved during a *sterilization* process in a controlled *sterilant receiving environment*.

It is respectfully submitted that the Examiner has failed to provide sufficient rationale to support a *prima facie* case of obviousness under 35 U.S.C. 103. As indicated above, Esch et al. and Priest differ significantly in that they are directed to very different environments (i.e., a fire atmosphere vs. a sterilant receiving environment), are directed to the detection of significantly different types of gasses (i.e., toxic gases produced in a fire vs. vaporized sterilant, e.g. vaporized hydrogen peroxide), and are used for different purposes (i.e., preventing injury to firefighters in fire atmospheres vs. verifying the effectiveness of a sterilization process).

**Wu and Moses et al.**

As indicated above, the Examiner has also rejected independent claims 10 and 28 as being obvious in view of the combined teachings of Wu, Moses et al., and Esch et al.

Wu discloses a test strip that is used for determining the peroxide or chlorine concentration of a test sample. The Examiner relies upon Wu for teaching "measurement of

peroxide concentrations in a *sterilization field* using a chemical indicator strip" (emphasis added).

Moses et al. discloses a gas analyzer for determining and recording continuously and intermittently the concentration of a gaseous material capable of reacting with a chemically-impregnated, gas-permeable tape or ribbon to change the light-reflecting power thereof. The Examiner relies upon Moses et al. for teaching "a continuous monitoring technique in a harsh environment, employing an indicator web or strip, which is moved through the enclosure containing the harsh environment. The apparatus is configured to automate the placement of an indicator strip within the environment to be tested."

The Examiner argues that "[i]t would have been obvious to one of ordinary skill in the art to employ means as taught in Moses et al., in the *sterilization system* of Wu because it would provide means for automated placement of the indicator strip to continuously monitor the *sterilizer* without exposing the user to the *sterilization environment*" (emphasis added). Accordingly, the Examiner characterizes Wu as a "*sterilization system*" for measuring peroxide concentrations in a "*sterilization field*."

Again, the Examiner argues that it would have been obvious to combine the teachings of Esch et al. with those of Wu and Moses et al. "because it would provide an inexpensive, yet accurate means of tracking the concentration and exposure time of the sterilization process in a staged, profiled manner." As discussed above in connection with independent claim 1, Esch et al. is directed to a badge for determining human exposure to toxic gases encountered in a *fire atmosphere*. Moreover, the Examiner's reliance upon the inexpensive cost for manufacturing the badge taught by Esch et al. as a basis for combining references is respectfully believed to be inadequate for supporting a *prima facie* case of obviousness under 35 U.S.C. 103.

In addition, it is unclear to which specific limitations recited in claims 10 and 28 the Examiner is applying the teachings of Moses et al. Clarification is respectfully requested in the event that this ground for rejection is not withdrawn.

In view of the lack of sufficient rational for combining Esch et al. with the other cited references, it is respectfully submitted that claims 10 and 28 are patentable over the prior art. Moreover, the remaining claims in the present application depend from claims 10 and 28.

Thus, it is respectfully submitted that these claims are likewise patentable over the prior art for at least the same reasons discussed in detail above in connection with independent claims 10 and 28.

In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters that need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8011US.

Respectfully submitted,

  
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